UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,425	03/31/2004	Bruce D. Hammock	02307O-142500US	8475

20350 7590 08/07/2008

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
POLANSKY, GREGG	
ART UNIT	**PAPER NUMBER**
1611	

MAIL DATE	DELIVERY MODE
08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,425	HAMMOCK ET AL.	
	Examiner	Art Unit	
	Gregg Polansky	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-18,25-34 and 41-50* is/are pending in the application.

4a) Of the above claim(s) *11-13,27-29 and 41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,14-18,25,26 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/18/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' response, filed 5/09/2008, to the Office Action mailed 2/20/2008 is acknowledged. Applicants canceled Claims 35-40 and presented arguments in response to the Office Action.

2. Claims 9-18, 25-34 and 41-50 are pending.

3. Claims 9, 10, 14-18, 25, 26 and 30-34 are presently under consideration.

4. Applicants' arguments have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 and 18 recite the limitation "[a] method of claim 9, wherein said EET is selected from…". There is insufficient antecedent basis for EET in Claim 9.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (WO 00/23060).

Erickson et al. teach treating immune/inflammatory related diseases such as, asthma, bronchitis, and obstructive airways disease (obstructive pulmonary disease) by the administration of inhibitors of soluble epoxide hydrolase, alone, or in combination with other therapeutic agents. See page 4, 1st full paragraph and "Summary of the Invention"; page 5, 1st three paragraphs; and page 22, claims 1-3. The generic requirement of an inhibitor of soluble epoxide hydrolase of instant Claim 9 is satisfied by the generic disclosure of an inhibitor of soluble epoxide hydrolase of Erickson et al.

Erickson et al. teach all of the limitations of instant Claims 9. Therefore, Claim 9 is properly rejected under 35 USC 102(b) as being anticipated by Erickson et al.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 9, 10, 14-18, 25, 26 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. (U.S. Patent Application Pub. No. 2003/0139469 A1), over Rose et al. (FASEB Journal, 2002, Vol. 16(12), pages 1660-1661).

Weiss et al. teach methods inhibiting proliferation of vascular smooth muscle (VSM) cell in a subject in need thereof with the administration of soluble epoxide hydrolase (sEH) inhibitors, preferably adamantyl dodecyl urea, N-cyclohexyl-N'-dodecyl urea (CDU), or N,N'-dicyclohexylurea (DCU). See page 1, paragraph 10. The reference teaches the sEH inhibitors may be used in combination with *cis*-epoxyeicosatrienoic acids (EETs). See pages 4-5, paragraph 57; and page 10, claim 17. Weiss et al. teach the synthesis, purification and use of the 8,9, 10,11, and 14,15 regioisomers of EET. See pages 6-7, paragraph 82; and page 8, paragraph 96. Since Weiss et al. do not teach the isolation of individual enantiomers of 14,15-EET, it is assumed that they utilize a racemic mixture of 14,15-EET. The isomer of 14,15-EET recited in instant Claims 18 and 32 (14R,15S-EET) is encompassed by the 14,15-EET racemate. The reference

teaches oral administration of the inhibitors. See page 6, paragraphs 69, 71, 74, and 75. Further, Weiss et al. teach an exemplary dose of a sEH inhibitor is from about 0.001 .mg/kg to about 100 mg/kg body weight of the mammal.; the dosage of the specific compound for treatment depends on many factors that are well known to those skilled in the art (e.g., the route of administration and the potency of the particular compound). Weiss et al. also teach a sustained release formulation of sEH inhibitors. See page 6, paragraph 78.

Weiss et al. do not teach methods of treating chronic obstructive pulmonary disease (COPD).

Rose et al. teach "[s]ustained generalized alveolar hypoxia as it occurs in chronic obstructive and restrictive lung disease…leads to pulmonary hypertension and cor pulmonale" and " is characterized by vascular smooth muscle cell (SMC) hyperplasia". See page 1660, 1st paragraph.

One of ordinary skill in the art at the time of the invention would have found it obvious to combine the teachings of Weiss et al. with those of Rose et al. to create a method of inhibiting the progression of COPD by the administration of sEH inhibitors (such as adamantyl dodecyl urea) alone, or in combination with EETs. One would have been motivated to do so to effectively inhibit the vascular smooth muscle cell proliferation seen in patients with COPD, thus inhibiting COPD induced pulmonary hypertension.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 9, 10, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (WO 00/23060), in view of Hammock et al. (U.S. Patent Application Pub. No. 2005/0026844 A1), further in view of Rose et al. (*supra*).

Erickson et al. teach treating immune/inflammatory related diseases such as, asthma, bronchitis, and other obstructive airways disease (obstructive pulmonary disease) by the administration of inhibitors of soluble epoxide hydrolase, alone, or in combination with other therapeutic agents (*supra*).

Erickson et al. do not teach the specific soluble epoxide hydrolase inhibitors or a slow release formulation of said inhibitors as recited by the instant claims.

The teachings of Rose et al. are presented *supra*.

Hammock et al. teach inhibitors of soluble epoxide hydrolase ("sEH") in methods of inhibiting diseases mediated by elevated levels of soluble epoxide hydrolase. Although the Hammock et al. reference discloses treatment of diseases such as chronic bronchitis, and COPD, the priority document (U.S. Provisional Application No.

60/460559) does not disclose treatment of these diseases. However, the priority application does disclose methods of treating diseases mediated by soluble epoxide hydrolase, comprising administering inhibitors of soluble epoxide hydrolase. See 60/460559 (hereinafter '559), page 10, claim 10. The '559 document discloses pulmonary hypertension to be treatable by this method. See page 17, paragraph 72. The Hammock et al. reference (2005/0026844) teaches *inter alia* the instantly elected sEH inhibitor, adamantyl dodecyl urea. See Abstract; Figure 1, compounds 192 and 686; pages 6-7, particularly paragraph 71; page 16, Example 6; and page 48, claim 48.

One of ordinary skill in the art would have found it obvious to utilize the Erickson et al. teachings of the use of soluble epoxide hydrolase inhibitors for the treatment of obstructive pulmonary diseases, along with the reference to Hammock et al. which teaches the use of soluble epoxide hydrolase inhibitors to treat diseases mediated by elevated levels of soluble epoxide hydrolase. One would have been motivated to do so because both reference teach treatment of diseases mediated by soluble epoxide hydrolase and a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. One of ordinary skill in the art would have known that pulmonary hypertension frequently occurs in patients with COPD (especially in view of Rose et al.) and therefore, treatment with a sEH inhibitor, as taught by '559, would be an effective treatment of COPD associated conditions. The '559 reference further teaches that the disclosed sEH inhibitors have improved solubility which facilitates formulation and delivery of these agents. See page 3, paragraphs 8 and 9.

Hammock et al. teach slow release formulations of the disclosed compositions. See page 12, lines 9-13 of the '559 document (sEH formulated in stents to facilitate slow release from the stents).

With respect to claimed dosage ranges of the active agents in the instant methods (i.e., Claim 34), it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(11).

One of ordinary skill in the art at the time of the invention would have found it obvious to utilize the teachings of Erickson et al. with those of Hammock et al. to treat diseases mediated by sEH , including immune/inflammatory related diseases, such as, asthma, bronchitis, and COPD with inhibitors of soluble epoxide hydrolase, such as adamantly dodecyl urea. One would have been motivated to combine teachings of Hammock et al. with those of Erickson et al. because Hammock et al. teaches sEH inhibitors potentially having better solubility thereby improving the formulation and delivery of said compounds. Further, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35

USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants argue the Hammock et al. reference (2005/0026844) "is not a proper anticipatory reference against the claims under examination" because the priority application which the Hammock et al. publication claims does not "disclose or suggest inhibiting the progression of obstructive pulmonary disease...by administering an inhibitor of sEH, alone or in combination with EET". The present 103(a) rejection of claims 9, 10, 14, and 15 over Erickson et al., in view of Hammock et al., and further in view of Rose et al. does not rely upon the Hammock et al. teaching of the treatment of chronic obstructive pulmonary disease.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 9, 10, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 111, 112, 114, 115, 120-122 of copending Application No. 11/685674. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to methods of treating lung disease with the administration of soluble epoxide hydrolase inhibitors, including those recited by the instant claims.

15. Claims 9, 10, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 10, 11 and 20 of copending Application No. 11/566171.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to methods of treating inflammation, including inflammatory disorders of the lungs, with the administration of soluble epoxide hydrolase inhibitors, including those recited by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have deferred responding to the above double patenting rejections "until there is an indication of allowable subject matter". Therefore, the rejections are maintained.

Conclusion

16. Claims 9, 10, 14-18, 25, 26 and 30-34 are rejected.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1611

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614